

- (b) growing plants from said collection of seed;
- (c) identifying said inbred plants;
- (d) selecting said inbred plant; and
- (e) controlling pollination in a manner which preserves the homozygosity of said inbred plant.

38. (Amended Twice) The method according to claim 37, wherein said maize plant having the physiological and morphological characteristics of the maize plant of line NP2052 further comprising a single gene transferred trait.

41. (Amended) The method according to claim 40, wherein said single gene trait comprises a Cry1Ab gene.

REMARKS

Applicant thanks the Examiner for the thorough review of Applicant's last Reply.

The Examiner has made a number of objections as set forth on page 3 of the Office Action. Applicant has amended the subject claims as suggested by the Examiner. With regard to claim 17, Applicant believes that it is not dependent on a rejected base claim.

Claims 6, 9-14, 16, 23, 24, 29, 30, and 38 stand rejected under 35 USC 112, second paragraph, as being indefinite.

In reference to claim 6, Applicant respectfully disagrees with the Examiner's assertion that 35 USC 112, second paragraph requires that the claims be limited to detasseling and transforming with a nucleic acid that confers male sterility.

The standard for whether a claim is definite is whether a person skilled in the art, reading the claim in light of the specification, will reasonably be apprised of the claim scope. *In re Warmerdam*, 33 F.3d 1354 (Fed. Cir. 1994). The primary purpose of the definiteness requirement in claims is to provide clear warning to others as to what constitutes infringement of the patent. *Solomon v. Kimberly-Clark Corp.* 216 F.3d 1372, 1379 (Fed. Cir. 2000). The Examiner states that it is not clear if the plant is male sterile because it has been detasseled, or whether it has been genetically manipulated. The concept of male sterility is well understood in the art. There are numerous means for obtaining male sterility, including cms (cytoplasmic male sterility) gms

(genomic male sterility), and the use of chemicals, as well as detasseling. There is no reason under 35 USC 112, second paragraph, that Applicant cannot broadly claim "male sterility," as the meaning of male sterility is clear to those skilled in the art, and the claim provides clear warning to others as to what constitutes infringement of the claim. Applicant respectfully requests that the Examiner withdraw this rejection.

Claims 9 and 11 have been amended to overcome the objection noted by the Examiner.

With regard to claim 16, Applicant is unsure of the rejection set forth. Applicant's previous reply has claim 16 as reciting "a plant." As a result, in this Reply, Applicant has amended "a maize plant according to claim 2" to read "the maize plant according to claim 2." Applicant respectfully submits that claim 2 provides the antecedent basis.

Claims 23 and 29 have been amended so that claims 23, 24, 29, and 30 depend from pending claims.

Claims 7, 8, 14, 15, 23, 24, 29, 30, 31, 35-39, and 43-49 are rejected under 35 USC 112, first paragraph, for failing to meet the written description requirement. In summary, claims 23, 24, 29, 30, 35, 36 and 49 are directed to F1 progeny. Pending claims 7, 8, 14, 15, 43, 45, are directed to plants of claim 2 or 5, wherein these plants further comprise a transgene or single gene transferred trait incorporated therein. Claims 31, 37, 38, 39, 44, 46, 47, and 48 are directed to methods for making the claimed plants.

With regard to claims 7, 8, 14, 15, 43, and 45, the Examiner states that the gene transferred traits and transgenes may be of any gene, including those that affect more than one trait, and that the morphological and physiological characteristics of any such plant comprising the single gene trait or transgene are not described. The Examiner states that, for example, a transgene that is a transcription factor can affect more than one gene, and multiple traits, and that such plants would express different morphological and physiological traits than those expressed by NP2052, wherein these traits are not described by the specification or prior art.

Applicant has amended the respective claims by deleting "one or more single gene transferred traits" and "one or more transgenes" and substituting therefore "a gene transferred trait" or "a transgene."

The amount of detail necessary to demonstrate possession of the invention varies depending on the predictability of the technology and the level of skill in the art. One skilled in the art, reading the original disclosure, must immediately discern the limitations at issue. Purdue

Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000)(citing Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994)). In a predictable technology, where one of ordinary skill in the art can predictably practice an invention with the disclosed method of making the invention, a less detailed description of the invention may be adequate. (Written Description Guidelines, 66 Fed. Reg. at 1106) For example, for a patent claim directed to a modem for modulating signals over telephone lines including a "timing means" element, the inventor was not required to describe the internal structure of processor programmed with a software timer. In re Hays Microcomputer Prods. Patent Lit., 982 F.2d 1527, 1533 (Fed. Cir. 1992). The Court found that one of ordinary skill in the art would know how to program a microprocessor to perform the necessary function described in the specification, and therefore the inventor was not required to disclose the details of the processor. Id. at 1533-34. It is important to note that persons skilled in the art would program the microprocessor differently, as it is recognized that there are a huge variety of ways to program a microprocessor(s) to get to the claimed produce or process. The Court clearly states that describing in general terms how a microprocessor would function, without detailing the actual programming to accomplish that function, meets the written description requirement, because one skilled in the art, based on current knowledge in the field, would know how to obtain the claimed invention.

Applicant respectfully submits that claimed phrases "a single gene transferred trait" and "a transgene" of the amended claims are sufficiently descriptive by themselves. In Union Oil Co. of Cal. V. Atlantic Richfield Co., 208 F.3d 989, 998, n.4 (Fed. Cir. 2000), the court confirmed that an originally filed claim can satisfy the written description requirement. The word "trait" obtained from a gene or transgene as claimed, combined with the novel line NP2052, describes the subject matter of the claims. Not unlike the ability of programmers to program a microprocessor without detailed instructions to perform a specific function, one skilled in the breeding and biotechnological arts knows how to incorporate genes into different germplasm to produce desired traits. In fact, one skilled in the art does not have to know the corresponding phenotype of a gene or transgene to be able to accomplish the incorporation: for example, by using marker assisted selection.

Although a claim may act as the written description, claims are properly read in context of the specification. In this case, the specification describes introgression or transformation of

specific genes and transgenes into maize plants and provides citations to patents and publications that include further and detailed disclosures of the art. As made clear in the specification, the breeding and biotechnological arts with regard to the claimed subject matter is advanced, making a detailed description of the phenotype characteristics of the "trait" unnecessary under 35 USC 112, first paragraph. It is also recognized in the art that genes incorporated into germplasm by introgression of transformation may cause phenotypic variations because of linkage disequilibrium and other effects. The fact that the end trait can vary in expression does not mean that the subject matter claimed is not sufficiently described, i.e., a trait resulting from the introgression of a gene or transgene. Again, the claimed subject matter is directed to technology that is relatively advanced and detailed descriptions are not required to apprise one skilled in the art that Applicant had possession of the invention as of the application filing date. Applicant respectfully requests that the Examiner withdraw its 35 U.S.C. 112, first paragraph rejection of claims 7, 8, 14, 15, 43, and 45.

Claims 23, 24, 29, 30, 35, 36 and 49 are also rejected under 35 USC 112, first paragraph. The Examiner states that the specification does not describe and progeny seeds or progeny plants of NP2052, and that the description of maize plant NP2052 does not provide any information concerning the description of any of its descendants. Applicant respectfully disagrees. The court in *Eli Lilly* case specifically states that what is required under 35 U.S.C. 112, first paragraph, is a description that distinguishes the claimed invention from other materials. Furthermore, the claimed seed of NP2052 represents the written description of the claimed subject matter of claims 1 and 2, as ruled in *Enzo Biochem v. Gen-Probe Incorporated*, 296 F.3d 1316, 1325 (Fed. Cir. 2002): "In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, P 1."

With regard to the claims directed to F1 hybrids made by crossing the inbred maize line NP2056 with different inbred maize lines, the specification (which includes the deposited seed of inbred maize line NP2056) certainly describes characteristics that are derived from NP2056. Those skilled in the art could easily distinguish any F1 hybrid made from NP2056 from any

hybrid that was not made from NP2056. In other words, the presence of $\frac{1}{2}$ the genome of NP2056 in a hybrid lines "**sufficiently distinguishes**" the genus of NP2056 derived hybrids from all other hybrids. No more is required under 35 USC 112, first paragraph, nor under *Eli Lilly*. Applicant respectfully submits that claims directed to F1 hybrids are sufficiently described pursuant to 35 USC 112, first paragraph, and that the rejection of claims 23, 24, 29, 30, 35, 36 and 49 be withdrawn.

The Examiner has rejected claims 31, 37, 38, 39, 44, 46, 47, and 48, which are directed to methods for making the claimed plants. In particular, the Examiner states that the methods to produce the claimed hybrid or other descendants of NP2052 do not describe the morphological and physiological traits of the plants and seeds themselves. Applicant respectfully submits that 35 U.S.C. 112, first paragraph, only requires that the **claimed invention** be described. Claims 31, 37, 38, 39, 44, 46, 47, and 48 are directed to method steps, which are described in detail in the specification, not to plants or seeds. On this basis, Applicant respectfully requests that the Examiner withdraw his 35 USC 112, first paragraph rejection of claims 31, 37, 38, 39, 44, 46, 47, and 48. Should the Examiner not be persuaded by Applicant in this matter, Applicant respectfully requests that the Examiner provide some support for his position that unclaimed subject matter must be described under 35 USC 112, first paragraph.

Claims 14, 40, and 41 stand rejected under 35 USC 112, first paragraph as not enabled. The Examiner states that the specification does not teach any NP2052 plants comprising single gene conversions. The Examiner further states that the specification does not teach how to introgress Bt-a11 or 176 events into the same location of the same chromosome of NP2052, and that it is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. The Examiner cites Hunsperger, Kraft, and Eshed for support. Applicant respectfully disagrees.

Introgression of a single transgene trait into elite germplasm from source material has been a standard practice in the art for many years. Attached to this Reply are several publications that describe standard plant breeding methods that are used to introgress a transgene into different genetic backgrounds.

Principles of Plant Breeding, 2nd Ed., Allard, A. (John Wiley & Sons, 1999) discusses in detail the use of backcrossing to introgress one or only a few specific characteristics into a superior variety:

The generally well adapted parent (the recurrent parent) into which an allele is to be substituted is involved in each backcross; the other parent (the donor parent) is involved in only the original cross. At the end of the backcrossing the allele (or alleles) being substituted will be heterozygous. Selfing after the last backcross produces a homozygosity for the allele (or alleles) being substituted and, coupled with selection, will result in a variety (or stock) with exactly, or very nearly exactly, the adaptedness, yielding ability, and quality characteristics of the recurrent parent but superior to that parent in respect to the particular characteristic(s) for which the improvement program was undertaken. Pg. 188

Also attached is a print out of University of Nebraska-Lincoln websites entitled *Overview of the Process of Plant Genetic Engineering and Backcross Breeding*. The *Overview* article briefly describes backcrossing of a transgene into an elite breeding line. In the *Backcross Breeding* article, the author discusses yield drag and yield lag. However, as the article discusses, these effects are not barriers to successfully introgressing a transgene into an elite variety.

The Examiner refers to Hunsperger, stating that this publication discloses a single gene trait in the genetic background of introgressed into the genetic background of another, that didn't result in the expected gene trait. Applicant respectfully points out that the Hunsperger publication is directed to work in Petunias, not corn. In addition, introgression of the gene was successful in the majority of genetic backgrounds. The fact that they were unable to obtain success in one experiment does not mean that it could not be accomplished with a second experiment. Furthermore, a claim cannot be rejected for lack of enablement "even though it listed elements that could form thousands of end products, some of which may not be operative. A claim may be invalid if the number of inoperative combinations becomes significant, forcing a person skilled in the art to experiment unduly to practice the claimed invention." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.* 750 F.2d 1569 (Fed. Cir. 1984). Applicant respectfully submits that introgressing a single transgene trait into different genetic backgrounds is well within the skill of persons skilled in the art, although admittedly it may require several generations of backcrossing and continual and careful selection of the desired phenotype. Applicant submits that the specification enables one skilled in the art to introgress a single gene trait from one genetic background to another.

The Examiner also recites the Kraft et al. article. The article is not really on point, because the purpose of backcross breeding is to break the linkage between closely linked genes by random recombination. After a number of backcross generations, the breakup of linkage disequilibrium will occur. It is also important to point out that even if phenotypic variations occur because of linkage

disequilibrium, the end plant product can still contain the selected single transgene expressing its gene product. The fact that the phenotype of the host plant is slightly changed does not mean the process of transgene introgression is not enabled.

Finally, the Examiner refers to Eshed et al. and epistatic interactions. Applicant points out that in the Eshed et al. article the experiments are based on introgressing large chromosome segments, quantitative trait loci, into otherwise homogenous backgrounds. See Fig. 4, which illustrates the large chromosome segments introgressed into nearly isogenic lines. The article simply does not apply to introgressing a single transgene trait from one genetic background into another. Applicant also points out that in the first paragraph of the Discussion section, the author states "QTL mapping studies in conventional segregation populations ... have generally uncovered little evidence for epistasis." Also, on page 1813, first column, the author states "the genetic constitution of the lines can be easily manipulated to generate shorter introgressions that retain the phenotypic effects." Applicant respectfully submits that the Eshed article, Hunsperger et al, nor Kraft et al. support the proposition that the introgression of a single transgene trait from one genetic background to another is not common in the maize breeding art. Applicant respectfully requests that the 35 U.S.C. 112, first paragraph, rejection of claims 14, 40, and 41 be withdrawn.

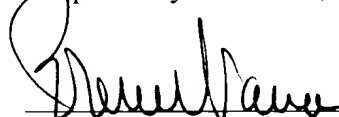
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version With Markings To Show Changes Made."**

In view of the above amendments and remarks, it is submitted that the application is ready for allowance. Early notice to this effect is solicited. If any additional information is needed, the Examiner is invited to call the undersigned attorney at (919) 541-8614.

Syngenta Biotechnology, Inc.
P.O. Box 12257
Research Triangle Park, NC 27709-2257

Date: February 18, 2003

Respectfully submitted,



Bruce Vrana, Reg. No. 38,672
Attorney for Applicant
Phone: (919) 541-8614

Version With Markings To Show Changes Made

In the claims:

Claim 45 has been cancelled.

The following claims have been amended:

7. (Twice Amended) The maize plant, or parts thereof, according to claim 2, further comprising [one or more] a single gene transferred trait[s].
8. (Twice Amended) The maize plant, or parts thereof, according to claim 2 [7, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more] further comprising a transgene[s] operably linked to one or more regulatory elements.
9. (Twice Amended) The maize plant according to claim [7] 8, wherein said [single] transgene [transferred trait comprises a gene] confers[ring] upon said maize plant tolerance to a herbicide.
11. (Twice Amended) The maize plant according to claim [7] 8, wherein said [single] transgene [transferred trait comprises a gene] confers[ring] upon said maize plant insect resistance, disease resistance or virus resistance.
15. (Amended) Seed of [a] the plant according to claim 7.
16. (Amended Twice) A tissue culture of regenerable cells of [a] the maize plant according to claim 2, wherein the tissue regenerates plants capable of expressing all the morphological and physiological characteristics of the plant according to claim 2.

18. The maize plant regenerated from the tissue culture of claim 16, wherein said plant is capable of expressing all the morphological and physiological characteristics of inbred line NP2052, seed of said inbred line having been deposited under ATCC Accession No: PTA-2660.

23. An F1 hybrid seed produced by the method of claim [20] 19.

29. An F1 hybrid seed produced by the method of claim [26] 25.

37. (Amended Twice) A method comprising:

(a) planting a collection of seed comprising seed of a hybrid, one of whose parents is [a] the plant according to claim 2, or a maize plant having all the physiological and morphological characteristics of a maize plant of line NP2052, said collection also comprising seed of said inbred line;

(b) growing plants from said collection of seed;

(c) identifying said inbred plants;

(d) selecting said inbred plant; and

(e) controlling pollination in a manner which preserves the homozygosity of said inbred plant.

38. (Amended Twice) [A] The method according to claim 37, wherein said maize plant having the physiological and morphological characteristics of the maize plant of line NP2052 further comprising [a plant according to claim 2, further comprising] a single gene transferred trait.

41. (Amended) The method according to claim 40, wherein said [a] single gene trait comprises a Cry1Ab gene.